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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,459	11/28/2000	Gopinathan K. Menon	680.0041USU	6235

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/723,459	MENON ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 28, 2004 has been entered.

Claims 1-38 have been cancelled.

Claims 39-70 are presented for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 57-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of sagging skin, fine lines/wrinkles, thinning skin, and dry skin, it does not reasonably provide enablement for preventing/ameliorating the effects of extrinsic and/or intrinsic aging on skin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: Claim 57 is drawn to a method of preventing/ameliorating the effects of extrinsic and/or intrinsic aging on skin comprising applying a composition comprising a crape myrtle extract to the skin. The nature of the invention is extremely complex in that it encompasses the actual prevention skin aging such that the subject treated with crape myrtle extract does not exhibit signs of skin aging.

Breath of the Claims: The complex of nature of the claim is greatly exacerbated by breath of the claim. The claims encompass prevention of skin aging, which have potentially many different causes (There are many causes for the accumulated cellular damage in the skin that we call aging. Among these are the oxidative processes and related free radical damage that result from UV sunlight, smog, toxins, cigarette smoke, X-rays, drugs, and other stressors). Each of these defects may or may not be addressed by the administration of the claimed composition.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually prevent skin aging is minimal. All of the guidance provided by the specification is directed towards treatment of skin aging rather than prevention of skin aging.

Working Examples: All of the working examples provided by the specification are directed toward the stimulation of fibroblasts in a cell culture.

State of the Art: While the state of the art is relatively high with regard to **treatment** of skin aging, the state of the art with regard to **prevention** of skin aging is deficient. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed composition was administered to a subject to **prevent** skin aging.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual **prevention** of skin aging in a human subject with the claimed composition makes practicing the claimed invention unpredictable in terms of prevention of skin aging.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for **prevention** of skin aging. If

unsuccessful, which is likely, given the lack of significant guidance from the specification or prior art with regard to prevention of skin aging in a mammal with any composition, one of skill in the art would have to then either envision a modification of the pharmaceutical composition of claim 1, composition dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding prevention of skin aging with any composition, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent the development of skin aging in a subject by administration of the claimed composition.

Therefore, a method of **preventing and/or ameliorating** the effects of extrinsic and/or intrinsic aging on skin comprising topically applying to the skin a composition comprising an effective amount of crape myrtle extract and at least one of the group consisting of vitamin A, vitamin C and bioflavonoids is not considered to be enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-70 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "bioflavonoids" in claims 39, 48, 49, 56, 57, 64, and 70 is a relative term, which renders the claims indefinite. The term "bioflavonoids" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "bioflavonoids" is indefinite. The examiner searched the term "bioflavonoids" which elicited several definitions for example:

a) naturally occurring pigments in fresh fruit;

b) any polyphenolic compounds that are ubiquitous in nature and are categorized, according to chemical structure, by having two benzene rings connected by a three carbon chain. The some important classes which are distinguished by the types of molecules found at the different numbered positions are flavonols, isoflavonols, flavones, flavonones, isoflavononones, isoflavones, anthocyandins, chalchones and catechins. Some important isoflavones include genistein, daidzein, and glycitein. Other important HMG-CoA reductase inhibitors from the isoflavones class of compounds are selected from the group consisting of ellagic acid, cathechin, qercetin, equol, epigallocathechin-3-gallate, resverstrol, quercetin and N-acetylcysteine;

c) isoflavonoids and flavonoid compounds contained in berries;

Since applicant has not defined what is meant by the term bioflavonoids, it is seen as indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 39-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leverett et al. U.S. Patent No. 5,980,904 A.

The claims are drawn to a composition comprising crape myrtle extract, in an effective amount to improve the aesthetic appearance of skin, scalp, and/or hair and at least one of the group consisting of vitamin A, vitamin C and bioflavonoids and a cosmetically acceptable vehicle.

Leverett et al. teach a topical composition comprising *inter alia* Lagerstroemia speciosa (crape myrtle extract) (column 4, lines 5-6), vitamin C derivatives (column 3,

lines 42-64), mulberry extract (column 2, lines 7-8)(a bioflavonoid as in definition (a) above which is naturally occurring pigments in fresh fruit) and retinoic acid, retinol and retinol esters (vitamin A) (column 6, lines 54-55).

It does not teach the quantity of 0.0001 to about 15 wt % of crape myrtle extract. However, the specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. For these and other self-evident reasons, it would have been obvious to employ the recited quantities of crepe myrtle extract.

Leverett et al. teach the composition in topical formulations such as an emulsion, linimint, ointment. Lotion, cream, solution, suspension, gel, stick, surfactant systems (shampoos) and the like (column 4, line 63 to column 5, line 4). Additional ingredients include humectants (column 6, lines 41-44), and sunscreens (column 6, lines 50-54).

It is noted that the composition of Leverett et al. is for the purpose of skin whitening. However, the intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed composition from the prior art composition. Since the crape myrtle extract composition of the patent is capable of performing the intended use of improving the aesthetic appearance of skin, scalp and/or hair, then it meets the claim.

2. Claims 49-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leverett et al. U.S. 5,980,904 A as applied to claims 39-48 above, and further in view of Mikimoto Pharmaceutical Co, LTD JP 07-126143, herein referred to as 07-126143.

The claims are drawn to a method of improving the aesthetic appearance of skin comprising topically applying to the skin, a composition having an effective amount of crape myrtle extract and at least one of the group consisting of vitamin A, vitamin C and bioflavonoids.

Leverett et al. teach the composition comprising Lagerstroemia speciosa (crape myrtle extract) along with optionally, a vitamin A, vitamin C and mulberry extract (a bioflavonoid).

It differs in that the instant claims are drawn to a method of improving the aesthetic appearance of skin. Leverett et al. is drawn to a method of skin whitening.

07-126143 teaches a method of using Lagerstroemia speciosa for preventing skin roughness, skin glossiness and skin tension. It would have been obvious to employ the composition of Leverett et al. for the purpose of improving the aesthetic appearance of skin motivated by the teaching of 07-126143 that Lagerstroemia speciosa is useful for preventing skin roughness, skin glossiness and skin tension, all of which would aesthetically improve skin appearance.

3. Claims 57-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leverett as applied to claims 39-48 above, and further in view of JP 2000072649 A herein referred to as 2000072649.

The claims are drawn to a method of preventing and/or ameliorating the effects of extrinsic and/or intrinsic aging on skin comprising topically applying to the skin, a composition having an effective amount of crape myrtle extract and at least one of the group consisting of vitamin A, vitamin C and bioflavonoids and a cosmetically acceptable vehicle.

Leverett et al. teach the composition comprising Lagerstroemia speciosa (crape myrtle extract) along with optionally, a vitamin A, vitamin C and mulberry extract (a bioflavonoid) to be applied to the skin for skin-whitening.

It differs in that the instant claims are drawn to preventing/ameliorating the effects of extrinsic/intrinsic aging. 2000072649 teach a method of applying a composition comprising Lagerstroemia speciosa for the purpose of maintaining elastic texture and youthfulness of the skin.

It would have been obvious to employ the composition of Leverett et al. for the purpose of improving the aesthetic appearance of skin motivated by the teaching of 2000072649 that Lagerstroemia speciosa is useful for maintaining elastic texture and youthfulness of the skin which would ameliorating the effects of extrinsic/intrinsic aging.

4. Claims 64-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leverett as applied to claims 39-48 above, and further in view of JP 07-138135 A herein referred to as 07-138135

The claims are drawn to a method of improving the aesthetic appearance of hair comprising topically applying to the hair, a composition having an effective amount of

crape myrtle extract and at least one of the group consisting of vitamin A, vitamin C and bioflavonoids and a cosmetically acceptable vehicle.

Leverett et al. teach the composition comprising Lagerstroemia speciosa (crape myrtle extract) along with optionally, a vitamin A, vitamin C and mulberry extract (a bioflavonoid) to be applied to the skin for skin-whitening.

It differs in that the instant claims are drawn to improving the aesthetic appearance of hair. 07-138135 teaches a method of applying a composition comprising Lagerstroemia speciosa as a hair lotion to the hair for the purpose of promote hair growth.

It would have been obvious to employ the composition of Leverett et al. for the purpose of improving the aesthetic appearance of hair motivated by the teaching of 07-138135 that Lagerstroemia speciosa is useful for promoting hair growth, which would improve the aesthetic appearance of the hair.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

The comments at page 9 of applicant's amendment filed 28 May 2004 have been considered as to the current grounds of rejection but are unpersuasive for the reasons indicated in the stated grounds of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday and Thursday from 9:00 A.M. - 7:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
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09/13/2004

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